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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,920	09/30/2003	Christopher P. Knapp	279.640US1	2079

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SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. BOX 2938
MINNEAPOLIS, MN 55402

EXAMINER	
SMITH, TERRI L	

ART UNIT	PAPER NUMBER
3762	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/675,920	KNAPP ET AL.	
	Examiner	Art Unit	
	Terri L. Smith	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-15* is/are allowed.

6)☒ Claim(s) *16-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 16 January 2007 has been entered.

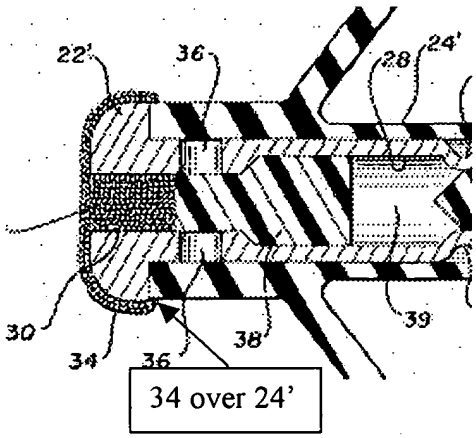
Response to Arguments

2. Applicant's arguments with respect to claims 1, 11, 35 and 40 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

3. Regarding Applicant's arguments against claims 30, 33 and 34, Examiner respectfully disagrees. As Examiner stated in the Advisory Action, in response to Applicant's argument that there is no suggestion to combine the references, the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the Stokes and Sirhan et al. references are in the same field of endeavor, specifically, an implantable device that elutes drugs, and therefore, they can reasonably be combined; and, as long as there are inventors, there will always be room for improvement to any invention. In response to Applicant's argument that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be

recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the Applicant's disclosure, such a reconstruction is proper. See In re McLaughlin, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Consequently, Examiner maintains the rejection for claims 30, 33 and 34 as submitted in the Office Action mailed on 13 October 2006 and restated herein below.

4. Regarding dependent claims 31 and 32, in response to Applicant's argument that the claims include each limitation of its parent claim and is not obvious over the cited references since the secondary references do not overcome the deficiencies of the primary references discussed above, Examiner respectfully disagrees. The Examiner has shown that the Applicant's arguments regarding parent claim 30 is not persuasive, and the Examiner maintains the rejection for these dependent claims as submitted in the Office Action mailed on 13 October 2006. However, in light of further examination, some of these claim limitations will be rejected differently still using the same references. Additionally, with respect to Applicant's argument under *Claims 19, 21, 22, 23, 24, 28, 29*, regarding "Stokes shows a sheath 24' and a porous coating 34, but the porous coating is not over the sheath," Examiner respectfully disagrees. The porous coating 34 is over the sheath shown in figure directly below.



Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the Applicant regards as his invention.

6. Claims 44–45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Claim 44 recites the limitation "the exterior". There is insufficient antecedent basis for this limitation in the claim.

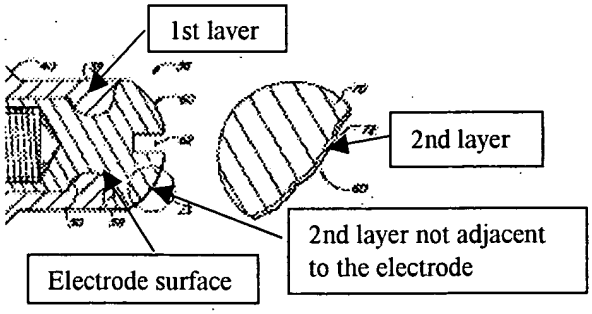
Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the Applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the Applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 1, 3, are rejected under 35 U.S.C. § 102(b) as being anticipated by Vachon et al., U.S. Patent 5,324,324.

9. Regarding claims 1 and 3, Vachon et al. disclose an electrical lead comprising a lead body and an electrical conductor (e.g., Fig. 1, element 22; column 3, lines 29–30); and an electrode coupled to an electrical conductor, wherein an electrode includes a coating on at least a portion of a surface of an electrode, a coating including two or more layers, with a first layer adjacent a surface of an electrode including an insulative material and a second layer adjacent a first layer and not adjacent to a surface of an electrode including at least one pharmacological agent (e.g., see figure below; column 4, lines 30–32; column 5, lines 62–64). [It is noted that the claim does not say the second layer covers the first layer or that the second layer is not adjacent the "entire" surface of the electrode.]



10. Claims 1, 3–7, 9, 10, 12–16, 18–23, 25, 35–37 and 41–44 are rejected under 35 U.S.C. § 102(b) as being anticipated by Vachon et al., U.S. Patent 6,405,091.

11. Regarding claims 1 and 3–7, Vachon et al. disclose an electrical lead comprising a lead body and an electrical conductor (e.g., Fig. 1, element 10); and an electrode coupled to an electrical conductor (e.g., 54, electrode), wherein an electrode includes a coating on at least a portion of a surface of an electrode (e.g., Fig. 2, element 62, insulative layer), a coating including

two or more layers (e.g., elements 90 and 92, tines which are molded as part of the insulative sheath 20, 74, drug dispensing collar, and 62, insulative layer) with a first layer adjacent a surface of an electrode including an insulative material (e.g., element 62) and a second layer adjacent a first layer and not adjacent to a surface of an electrode including at least one pharmacological agent (e.g., element 74; column 5, lines 43–45); a polymeric base coat on an electrode (e.g., 62; column 5, line 5) and a second layer comprises a matrix including a polymer and at least one pharmacological agent (e.g., element 74; column 5, lines 40–41 and 43–45; column 6, lines 60–61), wherein a second layer at least partially covers a polymeric base coat (e.g., Fig. 2, element 74, which Examiner is interpreting as a second layer partially covers element 62, which Examiner is interpreting as a polymeric base coat).

12. With respect to claims 9, 10 and 25, Vachon et al. disclose a third layer above a second layer wherein a third layer includes a porous barrier (e.g., Fig. 5, element 142 which Examiner is interpreting as a third layer and where Examiner takes the position that the polymer used to fabricate element 142 (polyurethane) meets the Applicant's specification for a porous barrier which discloses that "third layer includes a porous barrier including a polymeric coating" (see specification page 6, lines 5–6)).

13. Regarding claims 12–14, Vachon et al. disclose an outer layer includes at least one pharmacological agent (e.g., column 5, lines 40–41 and 43–45).

14. With respect to claim 15, a first layer is adapted to functionally increase an impedance of an electrode (e.g., column 5, lines 12–16 where exposing the electrode surface by first insulating it and then grinding the distal extremity to expose the disk-shaped active end surface serves to increase an impedance of an electrode).

15. Regarding claims 16, 21, 35, 41 and 44, Vachon et al. disclose an electrical pulse generator (e.g., Fig. 1, element 24); an electrical lead releasably coupled to electrical pulse generator (e.g., Fig. 1, element 10), wherein an electrical lead includes a lead body and an electrical conductor (e.g., Fig. 1, element 32, conductor); and an electrode coupled to an electrical conductor (e.g., Figs. 1–2, element 54), wherein an outer surface of an electrode is coated with two or more layers (e.g., 20, sheath, and 62, insulating layer and 74, drug dispensing collar; column 4, lines 9–11) comprising a first layer including an insulative material and comprises a polymeric base (e.g., 20, polyurethane sheath and 62, insulating layer) and a second layer over a first layer/coating a first layer of an electrode with a second layer (e.g., 74, drug dispensing collar), a second layer including a polymer at least one pharmacological agent and at least partially coats the first layer and an outer layer comprises at least one pharmacological agent (e.g., column 5, lines 43–45; column 6, lines 60–61).

16. With respect to claims 18, 19, 20, 22, 23, 36, 37, 42 and 43, Vachon et al. disclose a pharmacological agent comprises an anti-inflammatory agent wherein the agent is dexamethasone (e.g., column 5, lines 40–41 and 43–45).

17. Claims 35–45 are rejected under 35 U.S.C. 102(e) as being anticipated by Hossainy et al., U.S. Patent Application Publication 2003/0104028.

18. Hossainy et al. disclose coating an electrode with a first layer comprising a polymeric base coat (e.g., Fig. 2, element 6; paragraph [0025], lines 2–3 and 7; paragraph [0029], lines 1–2); and coating the first layer of the electrode with a second layer, wherein a second layer comprises a polymer and at least one pharmacological agent, and at least partially coats a first

layer (e.g., Fig. 2, element 7; paragraph [0027], lines 1–2 (claim 38); paragraph [0031] (claims 36 and 42); paragraph [0033], lines 1–2 (claims 36 and 42); paragraph [0034], lines 1–2 (claims 37 and 43); paragraph [0037], line 4 (claim 37 and 43)); a third layer comprises a porous barrier (claim 39) (e.g., Fig. 3, element 9; paragraph [0027], lines 1–3, where Examiner takes the position that the polymer used to fabricate layer 9 meets the Applicant's specification for a porous barrier which discloses that "third layer includes a porous barrier including a polymeric coating" (see specification page 6, lines 5–6)); a third layer regulates the release of the pharmacological agent from the matrix (claim 40) (e.g., Fig. 2, element 9; paragraph [0019], lines 4–7; paragraph [0022]); an outer layer comprises at least one pharmacological agent (claim 41) (e.g., Fig. 2, element 8; paragraph [0029], lines 31–32); contacting includes spraying (claim 45) (paragraph [0046], lines 4–5).

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

20. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the Examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

21. Claims 30, 33 and 34 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Stokes, U.S. Patent 4,506,680 in view of Sirhan et al., U.S. Patent Application 2003/0083646.

22. Regarding claim 30, Stokes discloses an electrical lead comprising a lead body and an electrical conductor (e.g., Fig. 1); and an electrode coupled to an electrical conductor (e.g., Figs. 1–2), wherein an electrode includes a coating on at least a portion of a surface of an electrode (e.g., 34 and 56) and implant of an electrode (e.g., column 3, lines 50–52). Stokes does not disclose a coating including three or more layers, with an inner layer including a pharmacological agent in a polymer matrix for regulated, chronic release of a pharmacological agent and an outer layer including only a pharmaceutical agent such that a pharmaceutical agent of an outer layer is exposed to tissue upon implant, and a middle layer between an inner layer and an outer layer, a middle layer including a porous polymer barrier. However, Sirhan et al. disclose a coating including three or more layers (e.g., Fig. 2I and 2K), with an inner layer including a pharmacological agent in a polymer matrix for regulated, chronic release of a pharmacological agent (e.g., 40) and an outer layer including only a pharmaceutical agent such that a pharmaceutical agent of an outer layer is exposed to tissue upon implant of an electrode (e.g., 55), and a middle layer between an inner layer and an outer layer, a middle layer including a porous polymer barrier (e.g., 43) to ensure optimum and efficient controlled substance delivery to the target tissue site. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Stokes to include a coating including three or more layers, with an inner layer including a pharmacological agent in a

polymer matrix for regulated, chronic release of a pharmacological agent and an outer layer including only a pharmaceutical agent such that a pharmaceutical agent of an outer layer is exposed to tissue upon implant, and a middle layer between an inner layer and an outer layer, a middle layer including a porous polymer barrier, as taught by Sirhan et al. to enhance controlled substance delivery to the target tissue site.

23. With respect to claims 33 and 34, Sirhan et al. disclose a pharmaceutical agent in a polymer matrix includes an anti-inflammatory drug (claim 33) (e.g., paragraph [0042], lines 1–3) and an anti-proliferative drug (claim 34) (e.g., paragraph [0042], lines 1–2 and 5–6).

24. Claims 2 and 17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Vachon et al. U.S. Patent 6,405,091.

25. Vachon et al. disclose the essential features of the claimed invention as described above except for an electrode includes a helical tip. However, it is well known in the art for an electrode to include a helical tip to ensure secure attachment of a lead to a target tissue for optimum therapy administration. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified invention of Vachon et al. to include an electrode includes a helical tip to ensure secure attachment of a lead for accurate, efficient and effective therapy administration.

26. Claims 8, 11, 24, 26–29 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Vachon et al. as applied to claims 5 and 21 above, and in view of Hossainy et al., U.S. Patent Application Publication 2003/0104028.

27. Regarding claims 8, 11, 24 and 26, Vachon et al. disclose the essential features of the claimed invention as described above except for a polymeric base coat is ethylene vinyl alcohol and a third layer comprises a porous barrier and regulates the release of a pharmacological agent from a matrix. However, Hossainy et al. disclose a polymeric base coat is ethylene vinyl alcohol (paragraph [0027], lines 1–2) and a third layer comprises a porous barrier (e.g., Fig. 3, element 9; paragraph [0027], lines 1–3, where Examiner takes the position that the polymer used to fabricate layer 9 meets the Applicant's specification for a porous barrier which discloses that "third layer includes a porous barrier including a polymeric coating" (see specification page 6, lines 5–6)) and regulates the release of a pharmacological agent from a matrix (e.g., Fig. 2, element 9; paragraph [0019], lines 4–7; paragraph [0022]) to facilitate ease of controlled therapeutic drug delivery and prolong the residence time of the drug in the patient. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Vachon et al. to include a polymeric base coat is ethylene vinyl alcohol, as taught by Hossainy et al. to provide effective and efficient therapeutic drug delivery.

28. With respect to claims 27–29, Vachon et al. disclose the essential features of the claimed invention as described above except for a fourth layer comprises at least one pharmacological agent and a pharmacological agent is an anti-inflammatory agent which is dexamethasone. However, Hossainy et al. disclose a fourth layer comprises at least one pharmacological agent and a pharmacological agent is an anti-inflammatory agent which is dexamethasone (e.g., Fig. 2, element 9; paragraph [0034], lines 1–2; paragraph [0037], line 4) to exert an effective therapeutic effect on the patient. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Vachon et al. to include a

fourth layer comprises at least one pharmacological agent and a pharmacological agent is an anti-inflammatory agent which is dexamethasone, as taught by Hossainy et al. to provide a robust therapeutic treatment on the patient.

29. Claim 31 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Stokes and Sirhan et al.

30. Stokes and Sirhan et al. disclose the essential features of the claimed invention as described above except for an electrode includes a helix. However, it is well known in the art for an electrode to include a helix to ensure secure attachment of a lead to a target tissue for optimum therapy administration. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the modified inventions of Stokes and Sirhan et al. to include an electrode includes a helix to ensure secure attachment of a lead for accurate, efficient and effective therapy administration.

31. Claim 32 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Stokes and Sirhan et al. as applied to claim 30 above, and further in view of MacGregor, U.S. Patent 4,281,669.

32. Stokes discloses an electrode (e.g., Figs. 2–3). Sirhan et al. disclose a third layer directly adjacent a surface (e.g., Figs. 2I and 2K, element 16). Stokes and Sirhan et al. do not disclose a polymer primer layer, with an inner layer adjacent a poly primer layer. However, MacGregor discloses a polymer primer layer, with an inner layer adjacent a poly primer layer (e.g., Fig. 2) to provide excellent wear and strength characteristics in the cardiovascular implant or device. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention

was made to have modified the modified inventions of Stokes and Sirhan et al. to include a polymer primer layer, with an inner layer adjacent a poly primer layer, as taught by MacGregor to enhance the electrode's function when implanted.

Conclusion

33. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is 571-272-7146. The Examiner can normally be reached on Monday - Friday, between 7:30 a.m. - 4:00 p.m..

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TLS
January 31, 2007
31 January 2007

Primary Examiner
3762
2/1/7